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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/730,232 | 12/08/2003 | Jackson Demond | 1001.1549101 | 2499 |

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| EXAMINER | |
|---|---|
| NEAL, TIMOTHY J | |
| ART UNIT | PAPER NUMBER |
| 3731 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/29/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/730,232 | DEMOND ET AL. | |
| | Examiner | Art Unit | |
| | Timothy J. Neal | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30 and 32-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26-30 and 32-57* is/are allowed.

6)☒ Claim(s) *1-8,13-21,25 and 58* is/are rejected.

7)☒ Claim(s) *9-12 and 22-24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This action is in response to amendments received on 12/04/2006. Currently claims 1-30 and 32-58 are pending. Claims 31 and 59 have been cancelled.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 4, 5, 7, 8, 18-21, 25, and 58** are rejected under 35 U.S.C. 102(e) as being anticipated by Dieck et al (US 6,425,909).

Dieck discloses:

1. An embolic filter assembly, said filter assembly comprising: at least one strand of wire forming a support hoop (Item 6); the strand of wire extending from said support hoop and forming at least one suspension strut (Fig 2); the suspension strut coupled, at least in part, to a guide wire or a filter wire or a tube (Fig 1 and Col 3 Line 60 – Col 4 Line 18); and a blood permeable sac having an opening, said opening fixedly attached to the support hoop, thereby forming a proximal opening or mouth of the embolic filter (Item 4 and Col 3 Line 60 – Col 4 Line 18); wherein the at least one suspension strut is at least in part, entwined around said guide wire or said filter wire, thereby forming a helix around the guide wire or filter wire (Item 21).

58. An embolic filter assembly, said filter assembly comprising: at least one strand of wire forming a support hoop (Item 6); the strand of wire extending from said support hoop and forming a suspension strut (Fig 2), wherein the suspension strut is comprised of the at least two sections of the strand of wire forming the support hoop (Fig 2); the suspension strut including a proximal portion of the at least two sections of the strand of wire coupled, at least in part, to a guide wire or a filter wire (Item 21); and a blood permeable sac having an opening (Item 4 and Col 3 Line 60 – Col 4 Line 18), said opening fixedly attached to the support hoop, thereby forming a proximal opening or mouth of the embolic filter (Fig 2); wherein the proximal portion of the at least two sections of the strand of wire includes one or more regions which are stamped flat (Col 3 Line 41).

Dieck also discloses the support hoop and suspension strut being nitinol (Col 3 Line 33), the filter defines a lumen with the guide wire moveably passing through the lumen comprised by the helix (Col 3 Line 60 – Col 4 Line 18), the helix is formed by entwining the strut in the distal to proximal direction (Item 21), emboli-laden blood enters the mouth or proximal opening of the embolic filter, and the emboli becomes entrapped within said blood permeable sac (functional language, no structural limitation), the at least one suspension strut is comprised of at least two sections of the strand of wire forming the support hoop (Fig 2), the at least one suspension strut has an articulation point whereafter the at least two sections of the strand of wire extend proximally for attachment to a guide wire or a filter wire (Fig 2), the at least two sections of the strand of wire proximal of the articulation point are entwined around the guide wire or lo the

filter wire, thereby forming a helix having the guide wire or the filter wire moveably passing through the lumen comprised by said helix (Fig 2), the at least two sections of the strand of wire proximal of the articulation point are weaved through one or more turns of wire forming a coil, and having the guide wire or the filter wire moveably passing through the lumen of the coil (Fig 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 2, 3, and 6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dieck et al '909.

Dieck discloses the invention substantially as claimed as stated above. Dieck does not explicitly disclose the support hoop self-expanding, having preformed shape, and comprising stainless steel. However, the Examiner considers it old and well known in the art to use stainless steel for embolic filters and to be a substitute for nitinol. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dieck's nitinol wire to be stainless steel. Also, the Examiner considers it old and well known to make embolic filters to be self-expanding and to have a preformed shape. Dieck does not disclose that the shape of the support hoop is preformed, but the hoop is biased to open into a circular shape. Therefore, it would have been obvious to a person having ordinary skill in the art at the

time the invention was made to modify Dieck's hoop to be self-expanding. Such a modification would not rely on actuation from the user and the wire would not have to connect to a pull mechanism at the proximal end. This would be a simpler design.

**Claims 13-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dieck et al '909 in view of Cano et al (US 6,893,451).

Dieck discloses the invention substantially as claimed as stated above. Dieck does not explicitly disclose the helix being covered with biocompatible material (heat shrink tubing, an adhesive, soldering material, or welding material). Cano teaches attaching the filter to the guide wire using a soldering technique (Col 9 Line 36). The Examiner considers the use of an adhesive, heat shrink tubing, and a welding material to be within the purview of one having ordinary skill in the art. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dieck's helix to be covered by a biocompatible material as taught by Cano. Such a modification would provide a means to attach the filter to the guide wire in a simple manner. Also, Dieck does suggest that the filter wire is attached to the guide wire in any manner (Col 4 Line 27). Therefore, a person having ordinary skill in the art would not have been excluded from using any of the well-known techniques claimed.

***Allowable Subject Matter***

Claims 26-30 and 32-57 are allowed.

Claims 9-12 and 22-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to show the strand of wire having two sections intertwined together. The sections of the strand of wire are joined, but not by intertwining. The prior art fails to show the struts extending through the lumen of a coil extending over a guide wire. The prior art fails to show the struts entwined around a tube with a guide wire moveable therethrough. The prior art fails to show struts having a zigzag shape. The prior art fails to show a biocompatible bead at the proximal ends of the wire. The prior art fails to show a tube with drilled holes with the ends of the wire placed in the holes. Also, the above stated limitations are not obvious modifications of the Dieck '909 reference.

***Response to Arguments***

Applicant's arguments, see pages 1-3, filed 12/04/2006, with respect to the rejection(s) of claim(s) 1, 6 and 58 under USC 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Dieck et al '909.

Dieck discloses the helical winding of the filter strut around the guide wire. This reads on the claims as stated above. Also, the limitation that the wire is "stamped" is a product-by-process limitation. The reference discloses a flat wire and therefore reads on the claim. The use of the various embodiments for covering the helix are all known

examples of means for attaching two elements and are therefore not patentable over the prior art. Making a filter self-expanding or requiring it to be actuated are the two most common embodiments of expanding filters. It is well within the purview of one having ordinary skill to modify either type of filter to include these limitations. Therefore, the claims are not patentable over the prior art. The two sections of the strand of wire can simply be interpreted as being split in half lengthwise. With this interpretation, the claims are not patentable over the prior art.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
1/22/07